Professional Labeling: The Prescribing Information

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Division of Drug Information Webinar Series – October 20, 2015

Learning Objectives

At the conclusion of this webinar, participants should be able to:

- Understand the purpose of the prescribing information (PI)
- Gain familiarity with the Physician Labeling Rule (PLR) format
- Understand major changes and improvements to the U.S. PI

Overview of Presentation

- What is the prescribing information?
- The two formats
  - Old format
  - PLR format
    - History/Goals
    - Content/Format changes
- Labeling examples

Prescribing Information

- Also known as professional labeling
- Summary of essential scientific information needed for safe and effective use of drug
- Written for health care provider, not patient

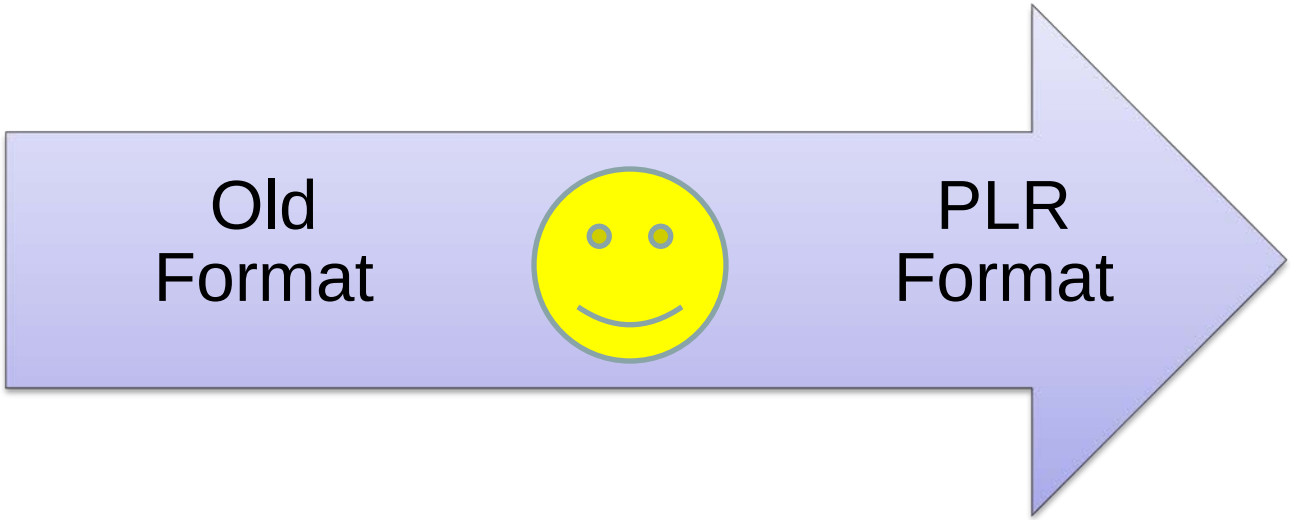
Prescribing Information

- Must be informative, accurate, and neither promotional in tone nor false or misleading

- Must be updated when new information becomes available

Prescribing Information

"Two Formats"



Old Format

Boxed Warning
Description
Clinical Pharmacology
Indications and Usage
Contraindications
Warnings
Precautions
- General
- Information for Patients
- Laboratory Tests
- Drug Interactions
- Drug/Laboratory Test Interactions
- Carcinogenesis, Mutagenesis, Impairment of Fertility
- Pregnancy
- Labor and Delivery
- Nursing Mothers
- Pediatric Use
- Geriatric Use

Adverse Reactions
Drug Abuse and Dependence
Overdosage
Dosage and Administration
How Supplied

- Limited format requirements
- NOT included:
  - Numbered sections or subsections
  - Table of Contents
  - Concise summary of important information
- Information NOT ordered according to clinical relevance
- Based on Final Rule 1979

Format: Old versus PLR

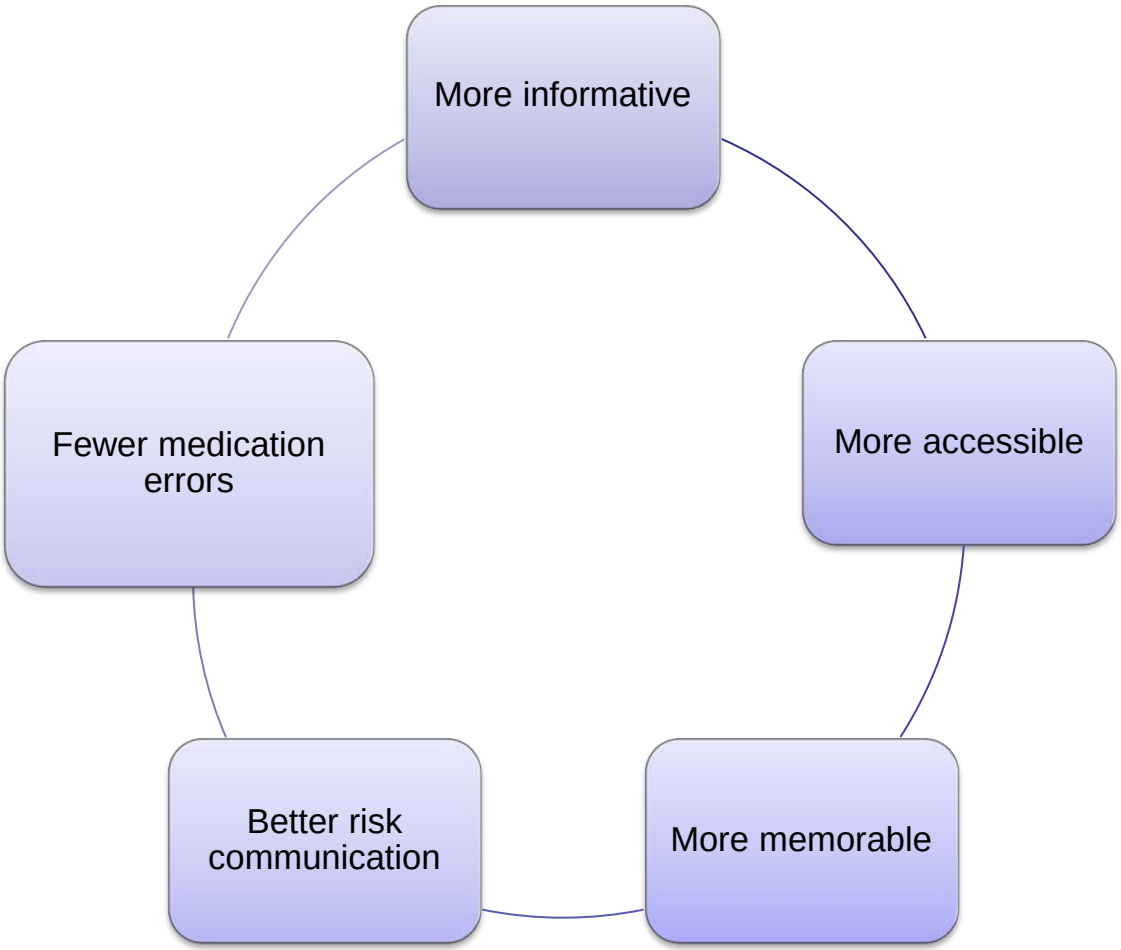
Location in Old Format	→	Location in FPI in PLR Format
Warnings	→	Warnings and Precautions
Precautions		
General	→	Warnings and Precautions
Information for Patients	→	Patient Counseling Information
Laboratory Tests	→	Warnings and Precautions
Drug Interactions	→	Drug Interactions
Drug/Laboratory Test Interactions	→	Warnings and Precautions
Carcinogenesis, Mutagenesis, Impairment of Fertility	→	Nonclinical Toxicology (Carcinogenesis, Mutagenesis, Impairment of Fertility)
Pregnancy	→	Use in Specific Populations (Pregnancy)
Labor and Delivery	→	Use in Specific Populations (Pregnancy)
Nursing Mothers	→	Use in Specific Populations (Lactation)
Pediatric Use	→	Use in Specific Populations (Pediatric Use)
Geriatric Use	→	Use in Specific Populations (Geriatric Use)
Adverse Reactions	→	Adverse Reactions

FPI = Full Prescribing Information

PLR: History

- In the 1990's, FDA organized national physician survey, focus groups, and held public meeting to understand how health care prescribers use PI:
  - What information is most important?
  - How can labeling be improved?
  - How is labeling information accessed?
- A labeling prototype was developed
- Proposed Rule published 2000
- Final Rule published 2006
  - Amended regulations about format and content of PI

PLR: Labeling Goals



PLR: Affected Products

- New Drug Applications (NDA), Biologics License Applications (BLA), and efficacy supplements approved on or after June 30, 2001:
  - 21 CFR 201.56 (General) and 201.57(Specific)

- Encourage voluntary submission at any time for older drugs approved prior to June 30, 2001
  - 21 CFR 201.80 (Specific)

- http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/LawsActsandRules/ucm084159.htm

PLR Requirements for Prescribing Information Website

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

A to Z Index | Follow FDA | En Español

Home | Food | Drugs | Medical Devices | Radiation-Emitting Products | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Tobacco Products

Drugs

Home > Drugs > Guidance, Compliance & Regulatory Information > Laws, Acts, and Rules

Laws, Acts, and Rules

- Complete Response Letter Final Rule
- Current and Proposed FDA Regulations Regarding the Use of Chlorofluorocarbons in Metered-Dose Inhalers
- Metered-Dose Inhalers Clean Air Act Information
- PLR Requirements for Prescribing Information

Resources for You

- Drugs@FDA
- FDA Online Label Repository
- Labeling Development Team

PLR Requirements for Prescribing Information

SHARE | TWEET | LINKEDIN | PIN IT | EMAIL | PRINT

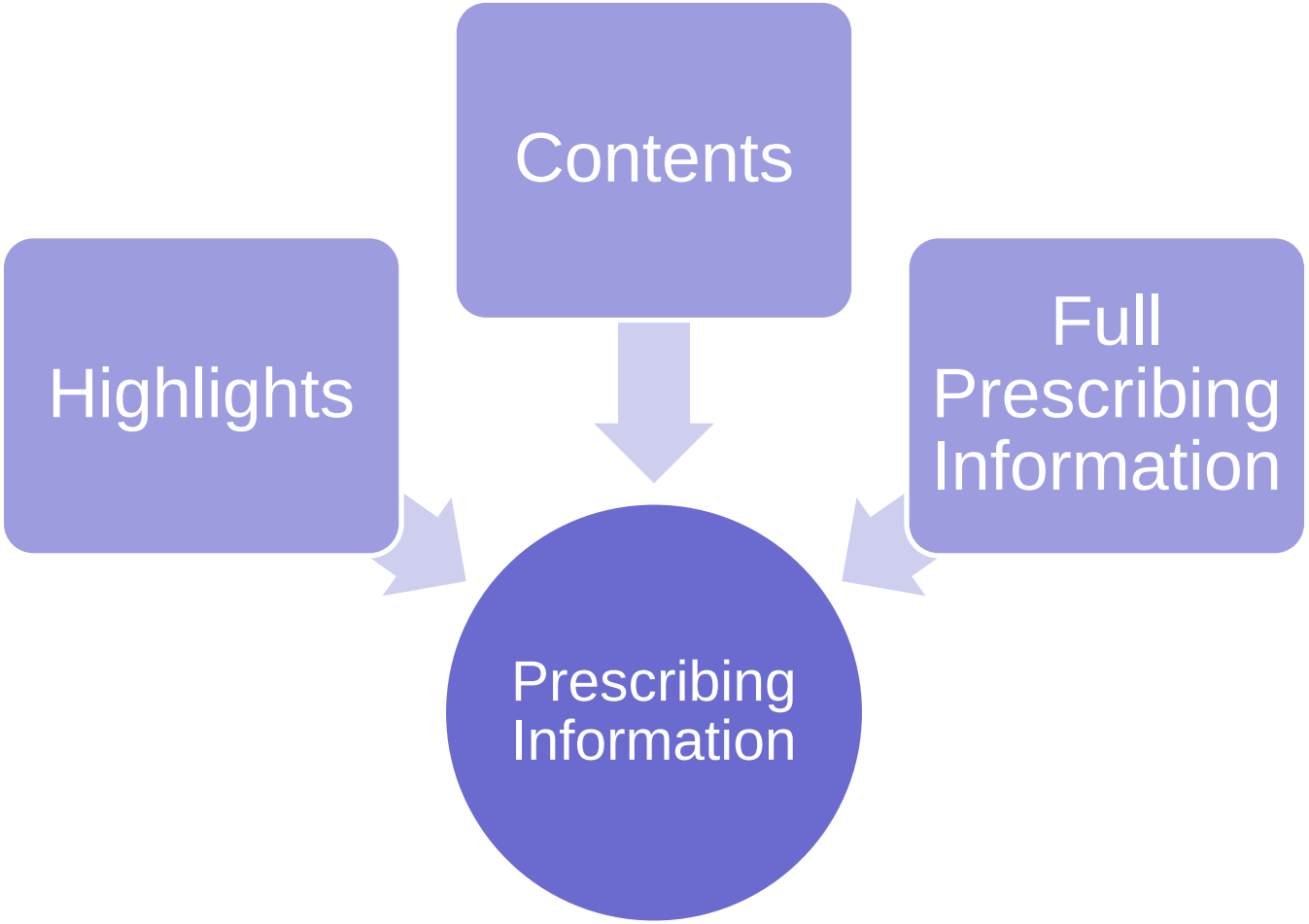
On January 24, 2006, the U.S. Food and Drug Administration (FDA) issued final regulations governing the content and format of prescribing information (PI) for human drug and biological products. The rule is commonly referred to as the "**Physician Labeling Rule**" (PLR) because it addresses prescription drug labeling that is used by prescribers and other health care providers.

The goal of the PLR content and format requirements as described at 21 CFR 201.56 and 201.57 is to enhance the safe and effective use of prescription drug products by providing health care providers with clear and concise PI that is easier to access, read, and use. The PLR format also makes PI more accessible for use with electronic prescribing tools and other electronic information resources.

PI submitted with new drug applications (NDAs), biologic license applications (BLAs), and efficacy supplements must conform to the content and format regulations found at 21 CFR 201.56 and 201.57. The Labeling Development Team works with review divisions to ensure PI conforms with the PLR. This page includes links to the Final Rule, regulations, related guidance documents, and additional labeling resources.

On December 3, 2014, the FDA published the Pregnancy and Lactation Labeling Rule (PLLR). The goal of the PLLR is to enhance the safe and effective use of prescription drug products in pregnant women, lactating women, and females and males of reproductive potential.

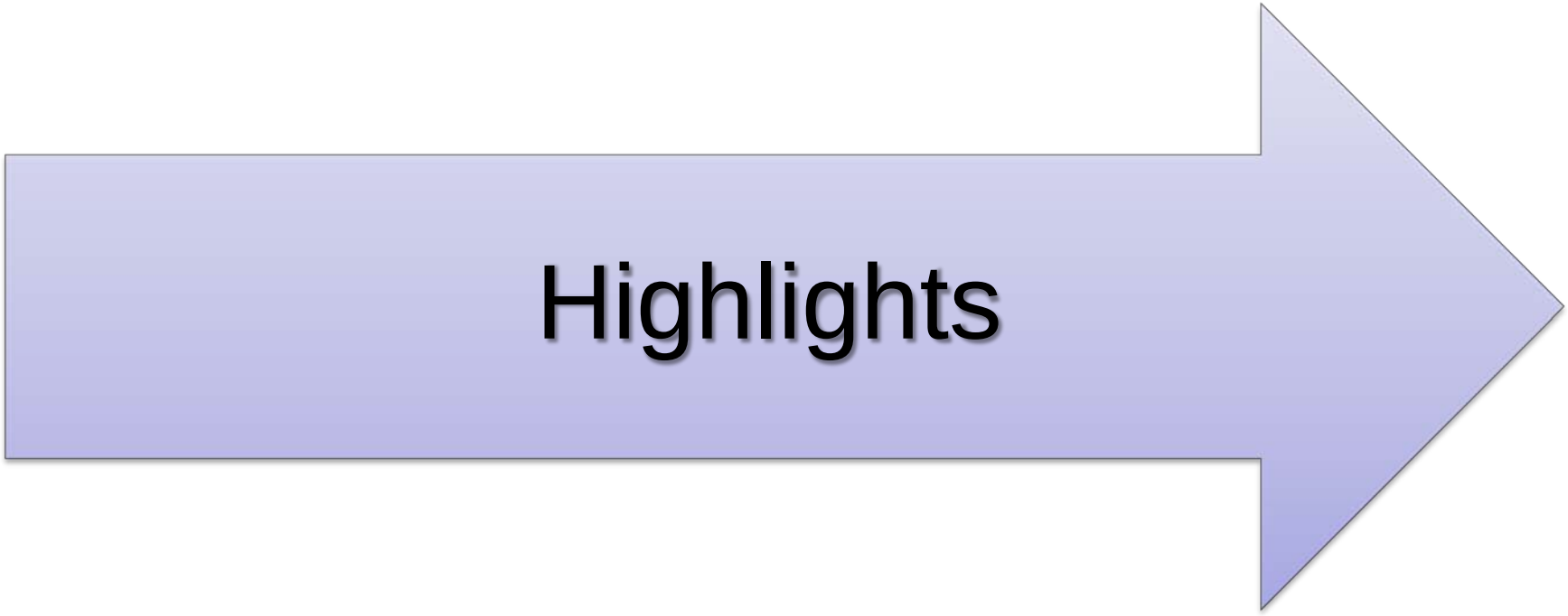
PLR Format: 3 Components



PLR Format: 3 Components

- **Highlights**
  - High level ½ page summary of critical information
  - Links to appropriate section of FPI
- **Contents**
  - Also known as “Table of Contents” (TOC)
  - Allows easy reference to FPI
- **Full Prescribing Information (FPI)**
  - Consistent order and numbering of sections
  - Frequently referenced information moved forward
  - Patient Counseling Information section now required

First Component



Sample Tool: Highlights

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use [DRUG NAME] safely and effectively. See full prescribing information for [DRUG NAME].

[DRUG NAME (nonproprietary name) dosage form, route of administration, controlled substance symbol]
Initial U.S. Approval: [year]

WARNING: [SUBJECT OF WARNING]
See full prescribing information for complete boxed warning.

- **[text]**
- **[text]**

----------RECENT MAJOR CHANGES----------
[section (X.X)] [m/year]
[section (X.X)] [m/year]

----------INDICATIONS AND USAGE----------
[DRUG NAME] is a [name of pharmacologic class] indicated for [text]

----------DOSAGE AND ADMINISTRATION----------
- [text]
- [text]

----------DOSAGE FORMS AND STRENGTHS----------
[text]

----------CONTRAINDICATIONS----------
- [text]
- [text]

----------WARNINGS AND PRECAUTIONS----------
- [text]
- [text]

----------ADVERSE REACTIONS----------
Most common adverse reactions (incidence > x%) are [text].

To report SUSPECTED ADVERSE REACTIONS, contact [name of manufacturer] at [phone #] or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------
- [text]
- [text]

----------USE IN SPECIFIC POPULATIONS----------
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[text]

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- [text]
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- [text]

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Revised: [m/year]

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----------DOSAGE AND ADMINISTRATION----------
- [text]
- [text]

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[text]

----------CONTRAINDICATIONS----------
- [text]
- [text]

----------WARNINGS AND PRECAUTIONS----------
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- [text]

----------USE IN SPECIFIC POPULATIONS----------
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Revised: [m/year]

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- [text]
- [text]

----------DOSAGE FORMS AND STRENGTHS----------
[text]

----------CONTRAINDICATIONS----------
- [text]
- [text]

----------WARNINGS AND PRECAUTIONS----------
- [text]
- [text]

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----------DRUG INTERACTIONS----------
- [text]
- [text]

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----------INDICATIONS AND USAGE----------
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----------DOSAGE AND ADMINISTRATION----------
- [text]
- [text]

----------DOSAGE FORMS AND STRENGTHS----------
[text]

----------CONTRAINDICATIONS----------
- [text]
- [text]

----------WARNINGS AND PRECAUTIONS----------
- [text]
- [text]

----------ADVERSE REACTIONS----------
Most common adverse reactions (incidence > x%) are [text].

To report SUSPECTED ADVERSE REACTIONS, contact [name of manufacturer] at [phone #] or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

----------DRUG INTERACTIONS----------
- [text]
- [text]

----------USE IN SPECIFIC POPULATIONS----------
- [text]
- [text]

See 17 for PATIENT COUNSELING INFORMATION [and FDA-approved patient labeling OR **and Medication Guide].**

Revised: [m/year]

Example: Highlights

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use HARVONI™ safely and effectively. See full prescribing information for HARVONI.

HARVONI™ (ledipasvir and sofosbuvir) tablets, for oral use
Initial U.S. Approval: 2014

----------INDICATIONS AND USAGE----------
HARVONI is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection in adults (1)

----------DOSAGE AND ADMINISTRATION----------
- Recommended dosage: One tablet (90 mg of ledipasvir and 400 mg of sofosbuvir) taken orally once daily with or without food (2.1)
- Recommended treatment duration (2.1):
  - Treatment-naïve with or without cirrhosis: 12 weeks
  - Treatment-experienced without cirrhosis: 12 weeks
  - Treatment-experienced with cirrhosis: 24 weeks
- A dose recommendation cannot be made for patients with severe renal impairment or end stage renal disease (2.2)

----------DOSAGE FORMS AND STRENGTHS----------
Tablets: 90 mg ledipasvir and 400 mg sofosbuvir. (3)

----------CONTRAINDICATIONS----------
None (4)

----------WARNINGS AND PRECAUTIONS----------
Use with other drugs containing sofosbuvir, including SOVALDI, is not recommended (5.2)

----------ADVERSE REACTIONS----------
The most common adverse reactions (incidence greater than or equal to 10%, all grades) observed with treatment with HARVONI for 8, 12, or 24 weeks are fatigue and headache (6.1)

To report SUSPECTED ADVERSE REACTIONS, contact Gilead Sciences, Inc. at 1-800-GILEAD-5 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

----------DRUG INTERACTIONS----------
- P-gp inducers (e.g., rifampin, St. John's wort): May alter concentrations of ledipasvir and sofosbuvir. Use of HARVONI with P-gp inducers is not recommended (5.1, 7, 12.3)
- Consult the full prescribing information prior to use for potential drug interactions (5.1, 7, 12.3)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 10/2014

Second Component

Sample Tool: Contents

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

Sample Tool: Contents

FULL PRESCRIBING INFORMATION: CONTENTS*

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Example: Contents

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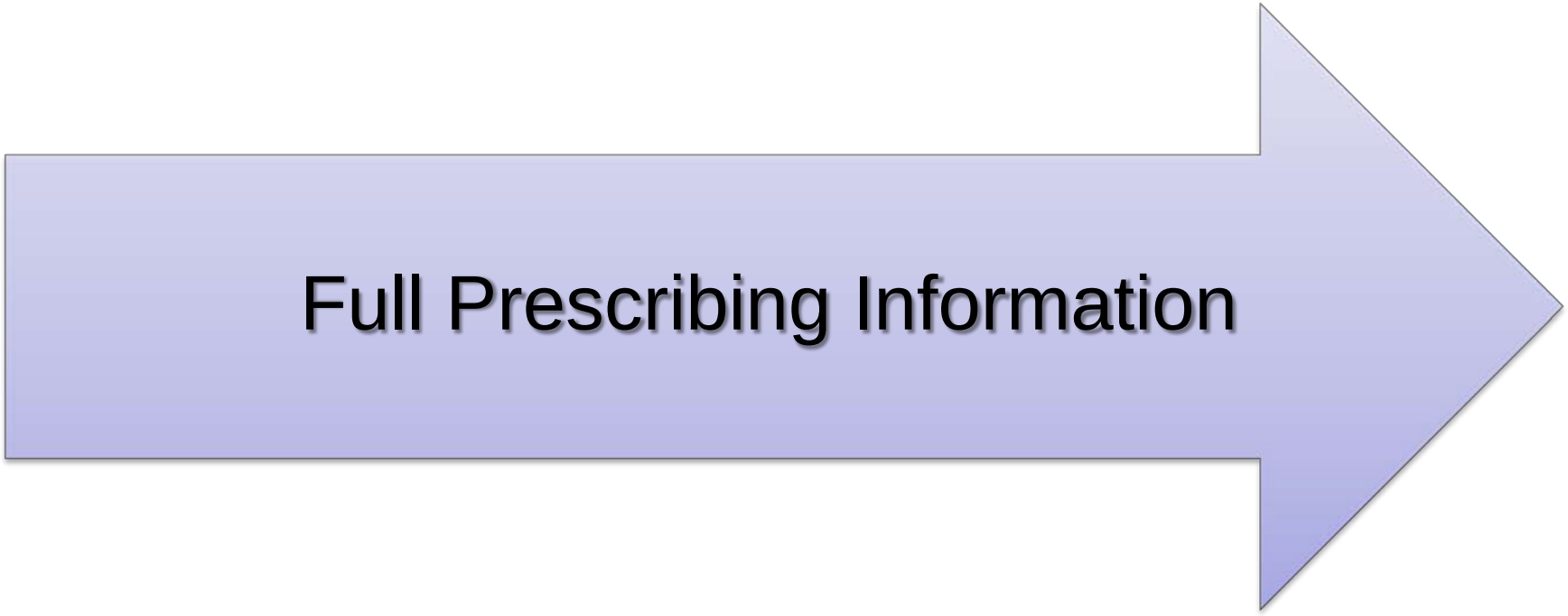
Third Component



Full Prescribing Information: New Sections of Labeling

- Created Dosage Forms and Strengths section
  - Formerly in How Supplied
- Warnings and Precautions consolidated into one section
- Formerly in Precautions, now new sections
  - Drug Interactions
  - Use in Specific Populations
  - Nonclinical Toxicology
  - Patient Counseling Information

Full Prescribing Information

BOXED WARNING
1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
6 ADVERSE REACTIONS
7 DRUG INTERACTIONS
8 USE IN SPECIFIC POPULATIONS
9 DRUG ABUSE AND DEPENDENCE
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
13 NONCLINICAL TOXICOLOGY
14 CLINICAL STUDIES
15 REFERENCES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

(FPI shortened for presentation purposes)

If a section or subsection designated by regulation is omitted, numbering must not change.

Labeling Sites

- Drugs@FDA
  - http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm
- FDA's online labeling repository
  - http://labels.fda.gov
- National Library of Medicine's DailyMed
  - http://dailymed.nlm.nih.gov

Questions?